UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF MICHIGAN
SOUTHERN DIVISION

FERNDALE LABORATORIES, INC.

Plaintiff,

vs.

VERACITY PHARMACEUTICALS, INC.
and BOCA PHARMACAL, INC.
Defendants.
_____/

Case No. 04-72900

HONORABLE DENISE PAGE HOOD
HONORABLE STEVEN D. PEPE

MEMORANDUM OPINION AND ORDER ON
DEFENDANT'S MOTION TO COMPEL THE PRODUCTION OF DOCUMENTS

Defendants have filed a motion to produce which has been referred for hearing and determination. The documents Defendants seek involve benzophenone and are the following:

> 1. Any and all correspondence between Ferndale and the Food and Drug Administration regarding benzophenone contamination of Ferndale's Locoid solution product.
>
> 2. Any and all test results regarding benzophenone contamination of Ferndale's Locoid solution product.
>
> 3. Any and all documents that refer, reflect, or relate to Ferndale's response to the benzophenone contamination of its Locoid solution product, including any documents related to any reformulation of Ferndale's Locoid solution product, and internal correspondence and/or memoranda regarding the contamination.
>
> 4. Any and all complaints or inquiries from pharmacists and/or physicians regarding benzophenone contamination of Ferndale's Locoid solution product.

Ferndale's Locoid solution is not presently involved in this litigation. Plaintiff contends these documents are not relevant and contain information not otherwise available to competitor pharmacal companies. This is a Lanham Act and Michigan Consumer Protection Act claim involving alleged false marketing and unfair competition against Defendants for their asserting that

Veracity's rectal creams, HC Pramoxine Rectal Cream 2.5% and HC Pramoxine Topical Cream 2.5%, are generic drugs for Plaintiff's Analpram IIC 2.5% cream. All three products apparently contain 1% pramoxine hydrocloride and 2/5% hydrocortizone acetate. Plaintiff's product is administered with a ApplicCoater injector with holes at the end and in the sides, Veracity's Pramoxine product is applied with an applicator with a hole solely at the end. All of the products can be applied with a finger. Plaintiff's testing indicates that Veracity's Pramoxine products had, at relevant times, the presence of benzophenone. The National Toxicology Program indicates that benzophenone is a potential liver carcinogen. It also may cause eye, skin and respiratory tract irritation. FDA has recalled it at certain concentrations from some products.

Plaintiff wishes to use the presence of benzophenone to argue that Veracity's Pramoxine products are not the generic equivalent of Analpram IIC. In raising the benzophenone issue Plaintiff asserted two possible arguments as to its relevance (Plaintiff's November 3, 2006, Motion for Leave to Supplement the Record, Dkt. # 24.). First, it made some indirect argument that its testing which discovered the benzophenone contaminant in Veracity's products demonstrates that Veracity did not do any clinical studies to prove bioequivalence – that the competing drugs "do not have significantly different rates and extent of absorption" – which Plaintiff asserts is needed for Defendants to claim the Pramoxine products are generics for Analpram IIC.

Of greater significance, Plaintiff argues that the presence of benzophenone in Veracity's products may result in Veracity's Pramoxine products having a different "safety profile" thus undercutting a claim of therapeutical equivalence needed to assert that the Pramoxine products are generics for Analpram IIC. While Plaintiff did report this benzophenone in Veracity's products to the Food and Drug Administration, it has investigated it and taken no action. Plaintiff's counsel at

the hearing indicated that at trial Plaintiff would not be asserting that Veracity's Pramoxine products are unsafe for use, nor referring to other products containing benzophenone being recalled. Rather Plaintiff will argue more narrowly that the presence of benzophenone in Veracity's Pramoxine products results in a different "safety profile" thus undercutting a claim the Pramoxine products are generics for Analpram IIC. The factual accuracy and the legal sufficiency of this claim by Plaintiff is yet to be resolved in litigation.

Defense counsel asserted that pharmacists are only concerned about whether the product is safe or not. Yet, even products deemed safe for marketing may have varying degrees of risk or safety for certain individuals.

If Plaintiff were accusing Defendants of marketing an unsafe product, it might be appropriate to allow Defendants to show that Plaintiff marketed a product with benzophenone at the same concentration levels. Here Ferndale's Locoid solution product, which is not involved in this litigation, at one time had a benzophenone problem and Plaintiff rectified the problem (apparently with the container of the product) to eliminate the benzophenone entirely. Yet, during the transition period Ferndale was not required to and chose not to recall the earlier produced Locoid solution on merchants' shelves that contained benzophenone. It is discovery on the benzophenone in Plaintiff's Locoid that Defendants seek.

Unless Plaintiff accused Veracity's products of being unsafe, the benzophenone level that was once in Locoid is not relevant to this litigation. Opening up discovery on Locoid unnecessarily expands the scope of discovery. I find under Fed. R. Civ. P. 26 (b)(2) that the costs and burdens of opening this area is discovery – with proofs and counter proofs, expert questions and expanded depositions – outweighs its likely benefit, taking into account the needs of the case and the limited

to non-existent relation to the important issues in this case. As Plaintiff presently asserts their anticipated proofs and use of benzophenone in Veracity's Pramoxine products, the presence in the past of benzophenone in Plaintiff's Locoid is not relevant, nor is discovery concerning this reasonably calculated to lead to the discovery of admissible evidence in this false marketing case. Introduction of evidence concerning benzophenone in Plaintiff's Locoid solution is also likely to cause avoidable confusion in the jury, although that ultimately is an evidentiary question for the trial judge, unlike the Rule 26 determination made in this opinion.

By way of example, assume Pharmaceutical Company A markets drug Alpha and drug Beta with Apha having no side effects or elements that are potential carcinogens, while drug Beta, which is used for a different purpose, (i.)contains a potential carcinogen that may, nonetheless, be marketed legally and (ii.) also causes stomach upset in some users. Assume further that Pharmaceutical Company B marketed drug Zeta as a generic for drug Alpha, but Zeta also contains a legally marketed potential carcinogen and like Beta causes stomach upset in some users. Pharmaceutical Company A should be able to bring a Lanham Act claim against Pharmaceutical Company B for falsely marketing Zeta as a generic for Alpha without hearing a word or enduring any discovery over its other, unrelated product Beta. The fact that Pharmaceutical Company A sells Beta with similar health related marketing limitations is not a defense for Pharmaceutical Company B to falsely suggest its product Zeta does not have those health related marketing problems and is a generic of Alpha. Only if Pharmaceutical Company A goes further and accuses Pharmaceutical Company B of selling an unsafe product in Zeta would Pharmaceutical Company A's sale of Beta with similar health risks potentially be relevant to its hypocrisy (e.g. credibility) and the factual correctness of its assertion. Simply stated the same is true here.

Accordingly, for the above stated reasons, as well as those stated on the record, Defendants' motion is DENIED. If Plaintiff's expert report suggests that Plaintiff's proofs regarding benzophenone in Veracity's Pramoxine products are different that noted above, Defendants may renew their motion.

Dated: March 15, 2006
Ann Arbor, Michigan

s/Steven D. Pepe
UNITED STATES MAGISTRATE JUDGE

Certificate of Service

I hereby certify that copies of this Opinion and Order were served upon the attorneys of record by electronic means or U. S. Mail on March 15, 2006.

s/William Truskowski
Courtroom Deputy Clerk